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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/786,905

02/24/2004

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212/562

4400

23371 7590 08/28/2007
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EXAMINER

PATTON, AMANDA K

ART UNIT

PAPER NUMBER

3762

MAIL DATE

DELIVERY MODE

08/28/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/786,905	Applicant(s) FOGARTY ET AL.	
	Examiner Amanda Patton	Art Unit 3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 February 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 February 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>24 February 2004</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3 and 4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 3 states, in lines 17-18, "providing a means for removing the balloon operably attached to the balloon". For the purposes of examination, it is assumed that the phrase should read. "providing a means for removing the means for delivering fluid operably attached to the balloon." Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 10, 16, and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Goetz (US Pat. 4,048,990).

Regarding **claim 1**, Goetz teaches a method of treating a patient comprising placing a cardiac massage device around the heart, and thus between the sternum and the heart during surgery within the chest of a patient, leaving the cardiac massage device in the patient after

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completing the surgery, conditionally operating the device if the heart stops, and removing the device after a perioperative procedure (e.g. Abstract, Col. 3, lines 14-32).

Regarding **claims 2 and 19**, Goetz teaches a method of treating a patient comprising providing a cardiac massage device adapted for cardiac massage within the chest of a patient during surgery including a balloon (heart massaging bladder 10) adapted to assume an inflated and deflated state wherein the balloon has a configuration sized and dimensioned to compress the heart when said balloon is inflated within the chest of the patient, a supply of fluid operably connected to the balloon through elongated tube 14 and source of pulsating pneumatic pressure 16 and constant pneumatic pressure 26, inserting the balloon around the heart and thus between the sternum and the heart and positioning the balloon so that, when inflated, the balloon will compress the heart, leaving the balloon in the patient after surgery, and conditionally operating the means for delivering fluid to repeatedly inflate and deflate the balloon if the patient's heart stops after the surgery (e.g. Abstract; Col. 2, lines 10-30; Col. 3, lines 13-32).

Regarding **claims 3 and 4**, Goetz additionally teaches removing the source of pneumatic pressure 26 from the support member 24, which is attached to heart massaging bladder 10, and removing the balloon through a very small opening in the patient's chest cavity after the overall incision has been substantially closed.

Regarding **claim 10**, Goetz additionally teaches a balloon, when its inflated state, that can be characterized by an anterior surface 24 not in direct contact with the heart and a posterior surface 24 in contact with the heart and facing the heart when the balloon is in place and inflated between the sternum and the heart, and the posterior surface further characterized by a palmate shape.

Regarding **claim 16**, Goetz additionally teaches a balloon structure wherein the balloon is characterized by a distal portion and a proximal portion. The balloon structure also comprising struts 30, connected to the balloon at least the distal end, that can be treated as a pull tab.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 5-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goetz. Goetz does not explicitly state that the step of performing surgery within the chest comprising performing open chest surgery. Goetz, does however, teach the ready removal of the heart massager through a very small opening in the patient's chest cavity after the overall incision has been substantially closed. It would have been obvious to one of ordinary skill in the art at the time the invention

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was made to also insert the device of Goetz during open chest surgery in order to provide the predictable results of a way to massage the heart both during and after surgery to aid the patient in recovery and assist during the event of cardiac arrest.

Claims 8-9, 11-15, and 17-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goetz in view of Johnson & Prisk (US Pat. 3,496,932).

Regarding **claim 8**, Goetz does not teach a diamond shaped balloon for insertion into the sternocostal space of a patient said diamond shaped balloon having an anterior surface and a posterior surface and a center axis running through the diamond shaped balloon. Johnson & Prisk, however, teach a substantially diamond shaped balloon characterized by anterior surface 28 and posterior surface 26 and a center axis defined by tip 32 and stem 30 (e.g. Figures 1-3; Col. 2, line 20 – Col. 3, line 35). Goetz additionally teaches a balloon comprising support rails 30 that are roughly parallel to the center axis. It would have been obvious to include the diamond-shaped balloon of Johnson & Prisk in the method of treating a patient of Goetz as well as the rails of Goetz in order to provide the predictable results of a device of effectively massaging the heart.

Regarding **claim 9**, Goetz does not teach a diamond shaped balloon for insertion into the sternocostal space of a patient, said diamond shaped balloon having an anterior surface and a posterior surface, the posterior surface of the device having pleats adapted to extend posteriorly from the diamond shaped balloon. Johnson & Prisk, however, teach a substantially diamond shaped balloon characterized by anterior surface 35 and posterior surface 26 wherein the posterior surface has pleats as shown in Figure 1. It would have been obvious to one of ordinary

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skill in the art at the time the invention was made to include the heart massaging device of Johnson & Prisk in the method of treating a patient of Goetz in order to provide the predictable results of effectively massaging the heart.

Regarding **claims 11-15**, Goetz does not teach a cardiac balloon wherein the posterior shape is further characterized by a convex shape. Johnson & Prisk, however, teach a cardiac massage device wherein the balloon is in its inflated state that is characterized by an anterior surface 28 and a posterior surface 26 facing the heart in which the posterior surface is characterized by a convex shape (e.g. Figure 2). It would have been obvious to one of ordinary skill in the art at the time the invention was made to include the heart massaging device of Johnson & Prisk in the method of treating a patient of Goetz in order to provide the predictable results of effectively massaging the heart.

Neither Johnson & Prisk nor Goetz expressly teach a balloon having a shape corresponding to a manta ray, a pillow, a sphere, or a bulb. It would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the method taught by Goetz and Johnson & Prisk with a balloon having a shape corresponding to a manta ray, a pillow, a sphere or a bulb, because Applicant has not disclosed that any of these shapes provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the balloon described in Johnson & Prisk, because it provides an effective way of massaging the heart and since it appears to be an arbitrary design consideration, which fails to patentably distinguish over Goetz and Johnson & Prisk. Therefore, it would have been an obvious matter of

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design choice to modify Goetz and Johnson & Prisk in order to obtain the invention as specified in the claims.

Regarding **claims 17 and 18**, Goetz does not teach a method step of providing a device comprising the further step of providing a rigid insertion rod attached to the balloon. Johnson & Prisk, however, teach a cardiac massage device using an insertion trocar and cannula assembly 35 attached to the balloon. Cannula 36 can be considered a rigid insertion rod. Since the tube is approximately 4 inches long and has a 10 inch radius of curvature, it has a bend of approximately 23 degrees from the plane of the balloon, which is approximately 15 degrees. It would have been obvious to one of ordinary skill in the art at the time the invention was made to include the heart massaging device of Johnson & Prisk in the method of treating a patient of Goetz in order to provide the predictable results of an insertion device capable of insertion of a device for effectively massaging the heart.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amanda Patton whose telephone number is (571) 270-1912. The examiner can normally be reached on Monday - Friday, 8:30am - 5:00pm, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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8/21/2007

GEORGE R. EVANISKO
PRIMARY EXAMINER

8/27/7